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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Mikszta et al.

Application No.: 10/679,038

Filed: October 2, 2003

For: INTRADERMAL DELIVERY OF  
VACCINE AND GENE THERAPEUTIC  
AGENTS VIA MICROCANNULA

Confirmation No.: 1660

Group Art Unit: 3763

Examiner: Manuel A. Mendez

Attorney Docket No.: 11219-029-999

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §1.56 AND §1.97**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 and §1.97 to inform the United States Patent and Trademark Office ("USPTO") of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Attorneys for Applicants hereby invite the Examiner's attention to references A01-A156, B01-B47 and C01-C142 listed on the attached form entitled "List of References Cited by Applicant."

Copies of references A155-A156, B01-B18, B21-B47, C01-C19, C22-25, C27-C35, C38-C58, C60-C69, C71-C81, C83-C84, C86-C93, C95-C98, C100-C104, C106, C108-C109, C111-C119, C122-C137 and C139-C142 are submitted herewith. Copies of references A01-A154 are not submitted herewith because they are U.S. patents or U.S. patent application publications. Pursuant to 37 C.F.R. § 1.98 (a)(2)(i) as amended (*see* Fed. Reg. vol. 69, no. 182, Sept. 21, 2004), the requirement for providing a copy of each U.S. patent or U.S. patent application publication listed in an Information Disclosure Statement in a patent application, regardless of the filing date of the application, is eliminated.

The above identified application is a continuation-in-part of U.S. application Serial No. 10/185,717 filed on July 1, 2002, now which is U.S. Publication No. 2002-0198509 which is a continuation-in-part of U.S. application Serial No. 09/835,243, filed April 13, 2001, now U.S. Patent No. 6,569,143. Pursuant to 37 C.F.R. § 1.98(d), copies of the listed

references B19-B20, and C20-C21, C26, C36-C37, C59, C70, C82, C85, C94, C99, C105, C107, C110, C120-C121 and C138 have not been included herein as such copies are available in the application Serial No. 09/835,243, filed April 13, 2001, now U.S. Patent No. 6,569,143. Applicants will provide copies of the references upon request by the Examiner.

Identification of the listed references is not meant to be construed as an admission of Applicants or Attorneys for Applicant that such references are available as "prior art" against the subject application.

Applicants respectfully request that the Examiner review the foregoing references and that the references be made of record in the file history of the application.

Pursuant to 37 C.F.R. § 1.97(b)(3), Applicants believe that no fee is due in connection with the filing of this Information Disclosure Statement. However, should the Patent Office determine otherwise, please charge the necessary fee to Jones Day Deposit Account No. 50-3013. A duplicate of this sheet is enclosed.

Date: July 13, 2006

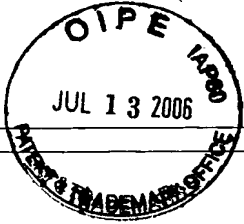
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Enclosure

## LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.  
11219-029-999  
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## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR
	A01	2005/0281832	12/22/2005	Campbell et al.	
	A02	2005/0255121	11/17/2005	Campbell et al.	
	A03	2005/0196380	09/08/2005	Mikszta et al.	
	A04	2005/0181033	08/18/2005	Dekker et al.	
	A05	2005/0180952	08/18/2005	Pettis et al.	
	A06	2005/0123550	06/09/2005	Laurent et al.	
	A07	US 2005/0096332	05/05/2005	Pettis, et al.	
	A08	US 2005/0096331	05/05/2005	Pettis, et al.	
	A09	US 2005/0096330	05/05/2005	Pettis, et al.	
	A10	2005/0008683	01/13/2005	Mikszta et al.	
	A11	US 2004/0175401	09/09/2004	Pinkerton	
	A12	US 2004/0170654	09/02/2004	Pinkerton	
	A13	2004/0131641	07/08/2004	Mikszta et al.	
	A14	2004/0120964	06/24/2004	Mikszta et al.	
	A15	2004/0082934	04/29/2004	Pettis et al.	
	A16	US 2004/0073160	04/15/2004	Pinkerton	
	A17	US 2004/0028707	02/12/2004	Pinkerton	
	A18	2003/0093040	05/15/2003	Mikszta et al.	
	A19	US 2003/0073609	04/17/2003	Pinkerton	
	A20	2002/0198509	12/26/2002	Mikszta et al.	
	A21	US 2002/0095134	07/18/ 2002	Pettis, et al.	
	A22	6,776,776	08/17/2004	Alchas et al.	
	A23	6,569,143	05/27/2003	Alchas et al.	
	A24	6,569,123	05/27/2003	Alchas et al.	
	A25	6,494,865	12/17/2002	Alchas	
	A26	6,808,506	10/2004	Lastovich et al.	
	A27	US 2002/0025326	02/28/2002	Blonder et al.	
	A28	6,623,457	09/2003	Rosenberg	
	A29	6,537,242	03/25/2003	Palmer, Phyllis J.	

EXAMINER

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR
	A30	6,534,065	03/18/2003	Makin et al.	
	A31	6,525,030	02/2003	Eriksson	
	A32	6,503,231	01/2003	Prausnitz et al.	
	A33	6,485,729	11/26/2002	Smith et al.	
	A34	6,482,176	11/19/2002	Wich	
	A35	6,099,504	08/08/2002	Gross, et al.	
	A36	6,372,223	04/16/2002	Kistner et al.	
	A37	6,346,095	02/12/2002	Gross, et al.	
	A38	6,334,856	01/01/2002	Allen, et al.	
	A39	6,319,230	11/2001	Palasis et al.	
	A40	6,319,224	11/20/2001	Stout, et al.	
	A41	6,213,977 B1	04/2001	Hjertman et al.	
	A42	6,210,369 B1	04/2001	Wilmot et al.	
	A43	6,200,291	03/13/2001	Di Pietro	
	A44	6,136,606	10/24/2000	Chatfield	
	A45	6,112,743 A	09/2000	Denton	
	A46	6,093,170 A	07/2000	Hsu et al.	
	A47	6,090,082 A	07/2000	King et al.	
	A48	6,090,080 A	07/2000	Jost et al.	
	A49	6,090,077 A	07/2000	Shaw	
	A50	6,083,197 A	07/2000	Umbaugh	
	A51	6,056,716	05/2/2000	D'Antonio, et al.	
	A52	6,053,893 A	04/2000	Bucher	
	A53	6,036,675 A	03/2000	Thorne et al.	
	A54	6,007,821	12/28/1999	Srivastava, et al.	
	A55	6,004,299 A	12/1999	Arai et al.	
	A56	6,001,089 A	12/1999	Burroughs et al.	
	A57	5,997,501	12/07/1999	Gross, et al.	
	A58	5,993,412 A	11/1999	Deily et al.	

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	A59	5,961,495 A	10/1999	Walters et al.	
	A60	5,957,897 A	09/1999	Jeffrey	
	A61	5,957,895	09/28/1999	Sage, et al.	
	A62	5,944,700 A	08/1999	Nguyen et al.	
	A63	5,928,207	07/27/1999	Pisano, et al.	
	A64	5,921,963 A	07/1999	Erez et al.	
	A65	5,912,000	06/15/1999	Podolski et al.	
	A66	5,893,397 A	04/1999	Peterson et al.	
	A67	5,891,085 A	04/1999	Lilley et al.	
	A68	5,879,327 A	03/1999	Moreau De Farges et al.	
	A69	5,879,326	03/09/1999	Godshall, et al.	
	A70	5,876,582	03/2/1999	Frazier	
	A71	5,873,856 A	02/1999	Hjertman et al.	
	A72	5,861,174	01/19/1999	Stratton et al.	
	A73	5,848,991	12/15/1998	Gross, et al.	
	A74	5,848,990	12/15/1998	Cirelli, et al.	
	A75	5,820,622	10/13/1998	Gross, et al.	
	A76	5,801,057	09/01/1998	Smart, et al.	
	A77	5,800,420	09/01/1998	Gross, et al.	
	A78	5,779,677 A	07/1998	Frezza	
	A79	5,704,911 A	01/1998	Parsons	
	A80	5,702,717	12/30/1997	Cha et al.	
	A81	5,702,362 A	12/1997	Herold et al.	
	A82	5,697,901 A	12/16/1997	Eriksson	
	A83	5,672,883 A	09/1997	Reich	
	A84	5,665,071 A	09/1997	Wyrick	
	A85	5,649,912 A	07/1997	Peterson	
	A86	5,599,302 A	02/1997	Lilley et al.	
	A87	5,591,139	01/07/1997	Lin, et al.	

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*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR
	A88	5,582,598	12/1996	Chanoch	
	A89	5,582,591	12/10/1996	Cheikh	
	A90	5,578,014 A	11/1996	Erez et al.	
	A91	5,569,189 A	10/1996	Parsons	
	A92	5,527,288	06/18/1996	Gross, et al.	
	A93	5,520,639 A	05/1996	Peterson et al.	
	A94	5,514,107 A	05/1996	Haber et al.	
	A95	5,503,627 A	04/1996	McKinnon et al.	
	A96	5,496,286 A	03/1996	Stiehl et al.	
	A97	5,480,381 A	01/1996	Weston	
	A98	5,466,220 A	11/1995	Brenneman	
	A99	5,437,647 A	08/1995	Firth et al.	
	A100	5,431,155 A	07/1995	Marelli	
	A101	5,417,662	05/23/1995	Hjertman, et al.	
	A102	5,383,851 A	01/1995	McKinnon, Jr. et al.	
	A103	5,368,578 A	11/1994	Covington et al.	
	A104	5,339,163 A	08/1994	Homma et al.	
	A105	5,334,144 A	08/1994	Alchas et al.	
	A106	5,331,954 A	07/1994	Rex et al.	
	A107	5,312,335 A	05/1994	McKinnon et al.	
	A108	5,292,506	03/08/1994	Oki et al.	
	A109	5,279,544	01/18/1994	Gross, et al.	
	A110	5,279,552	01/18/1994	Magnet	
	A111	5,250,023	10/5/1993	Lee, et al.	
	A112	5,222,949 A	06/1993	Kaldany	
	A113	5,195,526 A	03/1993	Michelson	
	A114	5,190,521 A	03/1993	Hubbard et al.	
	A115	5,156,591	10/20/1992	Gross, et al.	
	A116	5,147,328 A	09/1992	Dragosits et al.	

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## U.S. PATENT DOCUMENTS

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	A117	5,141,496 A	08/1992	Dalto et al.	
	A118	5,137,516 A	08/1992	Rand et al.	
	A119	5,098,389	03/24/1992	Cappucci	
	A120	5,071,353 A	12/1991	van der Wal	
	A121	5,064,413 A	11/1991	McKinnon et al.	
	A122	5,015,235 A	05/1991	Crossman	
	A123	5,003,987	04/2/1991	Grinwald	
	A124	4,978,344 A	12/1990	Dombrowski et al.	
	A125	4,955,871 A	09/1990	Thomas	
	A126	4,941,880 A	07/1990	Burns	
	A127	4,940,460 A	07/1990	Casey, I. et al.	
	A128	4,898,588 A	02/1990	Roberts	
	A129	4,886,499	12/12/1989	Cirelli, et al.	
	A130	4,883,573 A	11/1989	Thomas	
	A131	4,826,687	05/02/1989	Nerome et al.	
	A132	4,834,704 A	05/1989	Reinicke	
	A133	4,790,824 A	12/1988	Morrow et al.	
	A134	4,774,948 A	10/1988	Markham	
	A135	4,769,003 A	09/1988	Stamler	
	A136	4,592,753	06/03/1986	Panoz	
	A137	4,596,556 A	06/1986	Morrow et al.	
	A138	4,583,978 A	04/1986	Porat et al.	
	A139	4,468,223 A	08/1984	Minagawa et al.	
	A140	4,373,526 A	02/1983	King	
	A141	4,270,537	06/02/1981	Romaine	
	A142	4,060,073 A	11/1977	Collica et al.	
	A143	3,964,482	06/22/1976	Gerstel, et al.	
	A144	3,890,971 A	06/1975	Leeson et al.	
	A145	3,814,097	06/04/1974	Ganderton, et al.	

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	A146	3,400,715 A	09/1968	Pederson	
	A147	3,073,306 A	01/1963	Linder	
	A148	2,876,770 A	03/1959	White	
	A149	2,619,962	12/02/1952	Rosenthal	
	A150	2,569,901 A	10/2/1951	Richard	
	A151	2,559,474 A	07/3/1951	Son	
	A152	1,436,707 A	11/28/1922	Gaschke	
	A153	1,934,046 A	11/1933	Demarchi	
	A154	1,274,081 A	07/30/1918	Riethmueller	
	A155	09/606,909	06/29/2000	Pettis et al.	
	A156	11/006,086	12/06/2004	Campbell et al.	

**FOREIGN PATENT DOCUMENTS**

		FOREIGN PATENT DOCUMENT COUNTRY CODE, NUMBER, KIND CODE (IF KNOWN)	DATE	NAME	PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR	T
	B01	WO 03/002175	01/09/2003	Pharmacia Corporation		
	B02	WO 03/002069	01/09/2003	Becton, Dickinson, and Company		
	B03	WO 02/083232	10/24/2002	Becton, Dickinson, and Company		
	B04	WO 02/62321	08/15/2002	Ellipse Pharmaceuticals		
	B05	WO 02/11669	02/14/2002	Antigenics, LLC		
	B06	WO 01/98206	12/27/2001	RxKinetix, Inc.		
	B07	WO 01/80866	11/01/2001	Gauchet, Jean-Yves		
	B08	WO 01/35994	05/25/2001	Zonagen, Inc.		
	B09	EP 1 088 642	04/04/2001	Becton, Dickinson, and Company		
	B10	EP 1 086 719	03/28/2001	Becton, Dickinson, and Company		
	B11	EP 1 086 718	03/28/2001	Becton, Dickinson, and Company		
	B12	EP 1066848	01/2001	Asbaghi, Hooman A.		
	B13	WO 00/74763	12/14/2000	Georgia Tech Research Corporation		

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	B14	WO 00/67647	11/16/2000	Scimed Life Systems, Inc.		
	B15	WO 0056384	09/2000	Dugmore, Peter		
	B16	WO 00/54839	09/21/2000	Introgen Therapeutics, Inc.		
	B17	WO 00/29016	05/25/2000	Akzo Nobel, N.V.		
	B18	CA 2 349 431	05/25/2000	Akzo Nobel, N.V.		
	B19	JP 2000-37456	02/2000	Japan		
	B20	DE 29918794	02/2000	Germany		
	B21	WO 00/09186	02/24/2000	Medi-Ject Corporation		
	B22	WO 99/64580	12/16/1999	Georgia Tech Research Corporation		
	B23	WO 99/43350	09/02/1999	Iomai Corporation		
	B24	WO 9937345	07/1999	Restelli, Sergio		
	B25	WO 99/34850	07/1999	Fiderm S.R.L.		
	B26	WO 99/27986	06/1999	Disetronic Licensing AG		
	B27	WO 9925402	05/1999	Medico Development Investment Company		
	B28	EP 0 904 790 A2	03/1999	Becton, Dickinson, and Company		
	B29	WO 98/42374	10/01/1998	Zonagen, Inc.		
	B30	FR 2 612 401 A1	09/1988	Denance, Raymond		
	B31	WO 98/03196	01/29/1998	Merial		
	B32	WO 97/21457	06/19/1997	Elan Medical Technologies Limited		
	B33	WO 96/37155	11/28/1996	Silicon Microdevices, Inc.		
	B34	WO 96/37256	11/28/1996	Silicon Microdevices, Inc.		
	B35	EP 0 429 842	08/28/1996	Korea Research Institute of Chemical Technology		
	B36	WO 97/47323	12/18/1997	Zonagen, Inc.		
	B37	WO 97/37705	10/1997	Weston Medical Limited		
	B38	WO 97/13537	04/1997	Visionary Medical Products Incorporated		
	B39	WO 96/17648	06/13/1996	Cibageigy AG		
	B40	WO 95/01198	01/1995	Park, Ji		

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	B41	WO 94/23777	10/27/1994	Elan Medical Technologies Limited		
	B42	EP 02 79583 B1	10/1993	Owen Mumford Ltd.		
	B43	WO 9309826	05/1993	The Upjohn Company		
	B44	DE 41 27 887 C1	01/1993	Herbst, Manfred		
	B45	GB 2 206 794 A1	01/1989	Power, Richard		
	B46	GB 735538	08/1955	GB		
	B47	GB 725024	03/1955	Lilly and Co.		

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	T
	C01	"Flu vaccine: skin injection method effective in younger people," <i>American Health Line: Research Notes</i> (2004 Nov. 4)	
	C02	ALPAR et al., "Intranasal vaccination against plague, tetanus and diphtheria," <i>Advanced Drug Delivery Reviews</i> 51:173-201 (2001)	
	C03	AUTRET, et al., Comparison of Pharmacokinetics and tolerance of Calcitonine administered by Intradermal or Subcutaneous Route, <i>Fundamental Clinical Pharmacology</i> , Vol. 3, No. 2, pp 170-171, 1989	
	C04	AUTRET, et al., [Comparison of plasma concentration and tolerance of a single dose of human calcitonin by intradermal and subcutaneous administration], <i>Therapie</i> 46(1):5-8, 1991	
	C05	BADER et al., Influenza vaccine experience in Seattle. <i>Am. J. Public Health</i> . 1980 May;70(5):545	
	C06	BALDRICK, 2000, "Pharmaceutical excipient development: The need for preclinical guidance," <i>Regulatory Toxicology Pharmacol.</i> 32:210-218	
	C07	BELSHE et al., "Serum antibody responses after intradermal vaccination against influenza," <i>New England Journal of Medicine</i> 351(22):2286-2294 (2004)	
	C08	BENONI, et al., Distribution of Cefazidime in Ascitic Fluid, <i>Antimicrobial Agents and Chemotherapy</i> , Vol. 25, No. 6, June 1984, pp. 760-763	
	C09	BICKERS, et al., editors, <i>Clinical Pharmacology of Skin Disease</i> , pp. 57-90, Churchill Livingstone, Inc. 1984	
	C10	BLONDER et al., 1999, "Dose-dependent hyperlipidemia in rabbits following administration of poloxamer 407 gel," <i>Life Sci.</i> 65(21):PL261-266	
	C11	BOCCI, et al., The Lymphatic Route. IV. Pharmacokinetics of Human Recombinant Interferon $\alpha 2$ and Natural Interferon beta Administered Intradermally in Rabbits, <i>International Journal of Pharmaceutics</i> , 32, 1986, pp. 103-110 Elsevier Science Publishers B.V. (Biomedical Division)	
	C12	BRANSWELL, "Vaccine stretching may be an option for future shortages, pandemics: studies," <i>Canadian Press News Wire</i> (2004 Nov. 3)	
	C13	BRESSOLLE, et al., A Weibull Distribution Model for Intradermal Administration of Cefazidime, <i>Journal of</i>	

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**LIST OF REFERENCES CITED BY APPLICANT**

(Use several sheets if necessary)

ATTY. DOCKET NO.  
11219-029-999  
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3763

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	T
		Pharmaceutical Sciences, Vol. 82, No. 11, November 1993, pps. 1175-1178	
	C14	BRONAUGH et al., Methods for in Vitro Percutaneous Absorption Studies. II. Animal Models for Human Skin. Toxicol Appl. Pharmacol. 1982 Mar 15;62(3):481-8.	
	C15	BROOKS, et al., Intradermal administration of bivalent and monovalent influenza vaccines. Ann. Allergy. 1977 Aug; 39(2):110-2	
	C16	BROWN, et al., The immunizing effect of influenza A/New Jersey/76 (Hsw1N1) virus vaccine administered intradermally and intramuscularly to adults. J. Infect. Dis. 1977 Dec;136 Suppl:S466-71	
	C17	BRUKOTH, et al., Transdermal and Transmucosal Powered Drug Delivery, Critical Review™ in Therapeutic Drug Carrier Systems, 16 (4), (1999), pps. 331-384	
	C18	CALLEN, Intralesional Corticosteroids, Journal of the American Academy of Dermatology, University of Louisville School of Medicine, pp. 149-151, 1981	
	C19	CARLSSON et al., "Hepatitis A Vaccination by Intracutaneous Low Dose Administration: A less Expensive Alternative," Scand J Infect Dis; 1996;28(5):435-8	
	C20	CHALOUPKA et al., "Comparative Analysis of Six European Influenza Vaccines," Eur J Clin Microbiol Infect Dis; 1996 Feb;15(2):121-7	
	C21	CHATELET et al., "Clinical Immunogenicity And Tolerance Studies Of Liquid Vaccines Delivered By Jet-Injector And A New Single-Use Cartridge (Imule®): Comparison With Standard Syringe Injection," Vaccine; 1997;15(4)	
	C22	CHIN et al., 1996, "Manipulating systemic and mucosal immune responses with skin-deliverable adjuvants," J. Biotechnol. 44:13-19	
	C23	CHIN et al., 1993, "Manipulating mucosal immune response by intradermal immunization," J. Cell. Biochem. Supp. 17C:54, Abstract HZ 111	
	C24	CHIN et al., 1992, "Relationship between the immune response of sheep and the population dynamics of bacteria isolated from fleecerot lesions," Veterinary Microbiology 32:63-74	
	C25	CHRISTODOULIDES et al., "Effect of adjuvant composition on immune response to a multiple antigen peptide (MAP) containing a protective epitope from <i>Neisseria meningitidis</i> class 1 porin," Vaccine 18:131-139 (2000)	
	C26	CLARK et al., "Polyvalent influenza vaccine: comparison of jet injection with intradermal and subcutaneous syringe methods of administration," Oklahoma City, Oklahoma	
	C27	COESHOTT et al., 2001, "A novel adjuvant formulation containing a block copolymer with reverse gelation characteristics elicits long lasting IgG antibody responses after a single injection in mice," Abstracts of Submitted Papers, Fourth Ann. Conference Abstract S26	
	C28	CORBO M., et al, Transdermal Controlled Delivery of Propranolol from a Multilaminate Adhesive Device. Pharm Res. 1989 Sep;6(9):753-8.	
	C29	COSSUM, et al., Disposition of the C-Labeled Phosphorothioate Oligonucleotide ISIS 2105 after Intravenous Administration to Rats, The Journal of Pharmacology and Experimental Therapeutics, pp. 1181-1190, Vol. 267, No. 3, 1993	
	C30	COSSUM, et al., Pharmacokinetics of C-Labeled Phosphorothioate Oligonucleotide, ISIS 2105 after Administration to Rats, The Journal of Pharmacology and Experimental Therapeutics, pp. 89-94, Vol. 269, No. 1, 1994	
	C31	COUVREUR et al., "Multiple emulsion technology for the design of microspheres containing peptides and oligopeptides," Advanced Drug Delivery Review 28:85-96 (1997)	
	C32	CROOKE, et al., A Pharmacokinetic Evaluation of C-Labeled Afovirsen Sodium in Patients with Genital Warts,	

**EXAMINER****DATE CONSIDERED**

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ART UNIT

3763

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	T
		Clinical Pharmacology & Therapeutics, pp. 641-646, Vol. 56, No. 6, Part 1, December 1994	
	C33	CROWE, Experimental comparison of intradermal and subcutaneous vaccination with influenza vaccine. Am. J. Med. Technol. 1965 Nov-Dec;31(6):387-96	
	C34	DE SOUZA et al., "A novel adjuvant for use with a blood-stage malaria vaccine," <i>Vaccine</i> 13(14):1316-1319 (1995)	
	C35	DE SOUZA et al., "Cytokines and antibody subclass associated with protective immunity against blood-stage malaria in mice vaccinated with the C terminus of merozoite surface protein 1 plus a novel adjuvant," <i>Infection and Immunity</i> 64(9):3532-3536 (1996)	
	C36	DOWDLE et al., "Influenza immunization policies and practices in Japan," <i>J Infect Dis</i> ; 1980 Feb;141(2):258-64	
	C37	Efficacy of Intradermally Administered A2 Hong Kong Vaccine, <i>JAMA</i> ; 1970 July 6;213(1)	
	C38	FIROOZ, et al., Benefits and Risks of Intralesional Corticosteroid Injection in the Treatment of Dermatological Diseases, pp. 363-370, Vol. 20, No. 5, Clinical and Experimental Dermatology, Blackwell Science Ltd, September 1995	
	C39	FJERSTAD, "U. Minnesota professor uses alternative flu vaccine technique," <i>FSView &amp; Florida Flambeau via U-Wire</i> (2004 Nov. 15)	
	C40	FLYNN et al., "Influence of Needle Gauge in Mantoux Skin Testing," <i>Chest</i> ; 1994 Nov;106(5):1463-5	
	C41	FOY, et al., Efficacy of intradermally administered A2 Hong Kong vaccine. <i>JAMA</i> . 1970 Jul 6;213(1):130	
	C42	GLENN, et al., Advances in vaccine delivery: transcutaneous immunisation. <i>Exp. Opin. Invest. Drugs</i> 1999, 8(6):797-805	
	C43	GOODARZI, et al., Organ Distribution and Stability of Phosphorothioated Oligodeoxyribonucleotides in Mice, <i>Biopharmaceutics &amp; Drug Disposition</i> , pp. 221-227, Vol. 13, No. 3, John Wiley & Sons Ltd., April 1992	
	C44	GRAMZINSKI, et al., Immune response to a hepatitis B DNA vaccine in Aotus monkeys: a comparison of vaccine formulation, route, and method of administration. <i>Mol. Med.</i> 1998 Feb;4(2):109-18	
	C45	HAAS et al., 2002, "Developments in the area of bioadhesive drug delivery systems," <i>Expert Opin. Biol. Ther.</i> 2(3):287-298	
	C46	HALPERIN, et al., A comparison of the intradermal and subcutaneous routes of influenza vaccination with A/New Jersey/76 (swine flu) and A/Victoria/75: report of a study and review of the literature. <i>Am. J. Public Health</i> . 1979 Dec;69(12):1247-50	
	C47	HAYNES, et al., Ultra-long-duration Local Anesthesia Produced by Injection of Lecithin-coated Methoxyflurane Microdroplets, <i>Anesthesiology</i> , Vol. 63, Vol. 5. pp. 490-499, Nov. 1985	
	C48	HENDERSON et al., "Comparison of higherdose Intradermal Hepatitis B Vaccination to Standard Intramuscular Vaccination of Healthcare Workers," <i>Infect Control Hosp Epidemiol</i> ; 2000 Apr;21(4):264-9	
	C49	HENRY, et al., Microfabricated Microneedles: A Novel Approach to Transdermal Drug Delivery, <i>Journal of Pharmaceutical Sciences</i> , Vol. 87, No. 8, August 1998, pps. 922-925	
	C50	HERBERT, et al., Comparison of responses to influenza A/New Jersey/76-A/Victoria/75 virus vaccine administered intradermally or subcutaneously to adults with chronic respiratory disease. <i>J. Infect. Dis.</i> 1979 Aug;140(2):234-8	
	C51	HUNTER et al., 1981, "The adjuvant activity on nonionic block polymer surfactants. I. The role of hydrophile-lipophile balance," <i>J. Immunol.</i> 127(3):1244-1250	

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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(Use several sheets if necessary)

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October 2, 2003ART UNIT  
3763

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	T
	C52	HUNTER et al., 1984, "The adjuvant activity of nonionic block polymer surfactants. II. Antibody formation and inflammation related to the structure of triblock and octablock copolymers," J. Immunol. 133(6):3167-3175	
	C53	HUNTER et al., 1986, "The adjuvant activity of nonionic block polymer surfactants. III. Characterization of selected biologically active surfactants," Scand. J. Immunol. 23(3):287-300	
	C54	HUNTER et al., 1991, "Adjuvant activity of nonionic block copolymers. IV. Effect of molecular weight and formulation of titer and isotype of antibody," Vaccine 9:250-256	
	C55	HUNTER et al., 1994, "Mechanisms of action of nonionic block copolymer adjuvants," AIDS Res. Hum. Retroviruses 10(Supp. 2):S95-98	
	C56	HUNTER et al., 1995, "Copolymer adjuvant and titermax," in DES Stewart-Tull (ed.), The Theory and Practical Application of Adjuvants, John Wiley and Sons, New York pp. 51-94	
	C57	IIDA et al., 1987, "Stimulation of non-specific host resistance against Sendai virus and E. coli infections by chitin derivatives in mice," Vaccine 5(4):270-274	
	C58	ILLUM, 1998, "Chitosan and its use as a pharmaceutical excipient," Pharmaceutical Res. 15(9):1326-1331	
	C59	Injection Technique Intradermal	
	C60	International Search Report dated Dec. 20, 2001 for International Appln. No. PCT/US01/12251	
	C61	International Search Report dated Dec. 20, 2001 for International Appln. No. PCT/US01/12247	
	C62	International Search Report dated Dec. 20, 2001 for International Appln. No. PCT/US01/12248	
	C63	JABBAL-GILL et al., "Stimulation of mucosal and systemic antibody responses against <i>Bordetella pertussis</i> filamentous haemagglutinin and recombinant pertussis toxin after nasal administration with chitosan in mice," Vaccine 16(20):2039-2046 (1998)	
	C64	JAKOBSON et al., Variations in the Blood Concentration of 1,1,2-Trichloroethane by Percutaneous Absorption and Other Routes of Administration in the Guinea Pig, Vol. 41, No. 5, pp. 497-506, Acta Pharmacologica et Toxicologica, November 1977	
	C65	JARRATT, et al., The Effects of Intradermal Steroids on the Pituitary-Adrenal Axis and the Skin, The Journal of Investigative Dermatology, Vol. 62, No. 4, pp. 463-466, 1974	
	C66	KABANOV et al., "Pluronic® block copolymers: novel functional molecules for gene therapy," Advanced Drug Delivery Reviews 54:223-233 (2002)	
	C67	KATZ et al., 2000, "A nonionic block co-polymer adjuvant (CRL1005) enhances the immunogenicity and protective efficacy of inactivated influenza vaccine in young and aged mice," Vaccine 18(21):2177-2187	
	C68	KAUSHIK, et al., Transdermal Protein Delivery Using Microfabricated Microneedles, Oct/Nov 1999 (1 page)	
	C69	KE et al., 1997, "Nonionic triblock copolymers facilitate delivery of exogenous proteins into the MHC class I and class II processing pathways," Cell Immunol. 176(2):113-121	
	C70	KEELE et al., "Monographs of the Physiological Society No. 12: Substances Producing Pain and Itch," The Williams & Wilkins Company; 1964	
	C71	KENNEY et al., "Dose sparing with intradermal injection of influenza vaccine," New England Journal of Medicine 351(22):2295-2301 (2004)	
	C72	KERR, "Intradermal rabies vaccine more effective," Trends Microbiol, 2001;9(9):415	
	C73	KIDANE et al., "Effects of cellulose derivatives and poly(ethylene oxide) - poly(propylene oxide) tri-block copolymers (Pluronic® surfactants) on the properties of alginate based microspheres and their interactions with	

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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ART UNIT

3763

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	T
		phagocytic cells," Journal of Controlled Release 85:181-189 (2002)	
	C74	KIM et al., "Temperature-responsive and degradable hyaluronic acid/pluronic composite hydrogels for controlled release of human growth hormone," Journal of Controlled Release 80:69-77 (2002)	
	C75	KIRPATRICK, et al., Local Anesthetic Efficacy of Methoxyflurane Microdroplets in Man, Vol. 67, No. 3A, Anesthesiology, September 1987	
	C76	KNOX et al. "New research shows intradermal rather than intramuscular vaccine injection could stretch flu vaccine supplies," <i>National Public Radio: All Things Considered</i> (2004 Nov. 3)	
	C77	KOHN, "Flu shot technique yields more doses, studies find; critics say injecting skin rather than muscle is too difficult for common use," <i>The Baltimore Sun: Telegraph 3A</i> (2004 Nov. 4)	
	C78	LANIER et al., 1999, "Peptide vaccination using nonionic block copolymers induces protective anti-viral CTL responses," Vaccine 18(5-6):549-557	
	C79	LEROY, et al., Pharmacokinetics of Ceftazidime in Normal and Uremic Subjects, Antimicrobial Agents and Chemotherapy, Vol. 25, No. 5, pp. 638-642, May 1984	
	C80	MAJESKI et al., "Technique could stretch vaccine; changing the way shots are given means the current supply of flu vaccine could immunize 10 times as many people, two Minnesota physicians say" Saint Paul Pioneer Press: Main 1A (2004 Oct. 27)	
	C81	MAJESKI, "Alternate flu shot less effective in elderly; doctors proposed method to stretch vaccine supply," <i>Saint Paul Pioneer Press: Main 17A</i> (2004 Nov. 4)	
	C82	MARKS et al., "Intradermal Influenza Immunization, Experience with Hong Kong Vaccine," Am Rev Respir Dis; 1971 Apr;103(4):579-81	
	C83	MCALLISTER, et al., Solid and Hollow Microneedles for Transdermal Protein Delivery, Proceed. Int'l. Symp. Control. Rel. Bioact. Mater., 26 (Revised July 1999) Controlled Release Society, Inc. pp. 192-193	
	C84	McAllister, et al., Three-Dimensional Hollow Microneedle and Microtube Arrays, Conference: Solid-State Sensors and Actuators Transducers-Conference, 1999;10th, Vol. 12., pp 1098-1103	
	C85	MCCONNELL, "Clinical Do's & Don'ts—Giving Intradermal Injections"	
	C86	MCELROY, et al., Response to intradermal vaccination with A2, Hong Kong variant, influenza vaccine. N. Engl. J. Med. 1969 Nov 6;281(19):1076	
	C87	MCGUGAN, et al., Adrenal Suppression from Intradermal Triamcinolone. The Journal of Investigative Dermatology, Vol. 40, pp. 271-272, Baltimore, MD., 1963	
	C88	MCNEELA et al., "Manipulating the immune system: humoral versus cell-mediated immunity," <i>Advanced Drug Delivery Reviews</i> 51:43-54 (2001)	
	C89	Merriam-Webster's Collegiate Dictionary, 10 <sup>th</sup> Edition, 1998, Merriam-Webster, Inc., Springfield, MA, p. 306	
	C90	MOGHIMI et al., "Poloxamers and poloxamines in nanoparticle engineering and experimental medicine," <i>Tibtech</i> 18:412-420 (2000)	
	C91	MOGHIMI et al., 1996, "Poloxamer-188 revisited: a potentially valuable immune modulator," J. Natl. Cancer Inst. 88(11):766-768	
	C92	MONTAGNE et al., "Intradermal influenza vaccination - can less be more?" New England Journal of Medicine 351(22):2330-2332 (2004)	
	C93	MURILLO et al., "Modulation of the cellular immune response after oral or subcutaneous immunization with microparticles containing <i>Brucella ovis</i> antigens," <i>Journal of Controlled Release</i> 85:237-246 (2002)	
	C94	NAGAFUCHI et al., "Intradermal Administration of Viral Vaccines," Rev Med Virol; 1998 Apr;8(2):97-111	

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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3763**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	T
		(Abstract)	
	C95	NEWMAN et al., 1998, "Design and development of adjuvant-active nonionic block copolymers," J. Pharm. Sci. 87(11):1357-1362	
	C96	NEWMAN et al., 1998, Development of adjuvant-active nonionic block copolymers," Adv. Drug Deliv. Rev. 32(3):199-223	
	C97	NEWMAN et al., 1998, "Use of nonionic block copolymers in vaccines and therapeutics," Crit. Rev. Ther. Drug Carrier Syst. 15(2):89-142	
	C98	NEWMAN et al., 1997, "Increasing the immunogenicity of a trivalent influenza vaccine with adjuvant active nonionic block copolymers for potential use in elderly," Mech. Ageing Dev. 93:189-203	
	C99	NICKOLOFF, "Dermal Immune System" (undated)	
	C100	NICULESCU, et al. Efficacy of an adsorbed trivalent split influenza vaccine administered by intradermal route. Arch. Roum. Path. Exp. Microbiol. 1981, 40(1):67-70	
	C101	NISHIMURA et al., 1984, "Immunological activity of chitin and its derivatives," Vaccine 2:93-99	
	C102	PAYLER DK., Intradermal influenza vaccine using Portojet 1976. Br. Med. J. 1977 Oct 29;2(6095):1152	
	C103	PAYLER, et al., Letter: Intradermal influenza vaccination. Br. Med. J. 1974 Jun 29;2(921):727	
	C104	PEPPAS et al., 1996, "Hydrogels as mucoadhesive and bioadhesive materials: a review," Biomaterials 17(16):1553-1561	
	C105	PHILLIPS et al., "Purified Influenza Vaccine: Clinical and Serologic Responses to Varying Doses and Different Routes of Immunization," Department of Medicine and Community Medicine, University of Vermont College of Medicine, Burlington, Vermont, J Infect Dis; 1970 Jul-Aug;122(1):26-32	
	C106	PLAYFORD et al., "Intradermal recombinant hepatitis B vaccine for healthcare workers who fail to respond to intramuscular vaccine," Infect Control Hosp Epidemiol. 2002 Feb;23(2):87-90	
	C107	POLILIO et al., "Does a Needleless Injection System Reduce Anxiety in Children Receiving Intramuscular Injections?," Pediatric Primary Care Clinic, Boston City Hospital, MA, USA.; Pediatr Nurs.; Jan.-Feb. 1997;23(1):46-9	
	C108	PROPST et al., "Reinforced intradermal hepatitis B Vaccination in Hemodialysis Patients is Superior in Antibody Response to Intramuscular or Subcutaneous Vaccination," Am J Kidney Dis; 1998 Dec;32(6):1041-5	
	C109	RAHMAN et al., "Cellular and Humoral Immune Responses Induced by Intradermal or Intramuscular Vaccination with the major Hepatitis B Surface Antigen," Hepatology; 2000 Feb;31(2):521-7	
	C110	RENFREY et al., "Morphological and Biochemical Characterization of Influenza Vaccines Commercially Available in the United Kingdom," Vaccine; 1994;12(8)	
	C111	RINDFLEISCH et al., "La Crosse finding could curtail flu vaccine shortages," Wisconsin State Journal D9 (2004 Nov. 14)	
	C112	ROBINSON et al., 1987, "Bioadhesive polymers for controlled drug delivery," Ann NY Acad. Sci. 507:307-314	
	C113	ROPAC et al., "Immunization against Hepatitis B: comparison of immune response to intradermal, intramuscular, and combined vaccination," Periodicum Bilogorum; 2001;103(1):39-43	
	C114	RYAN et al., "Immunomodulators and delivery systems for vaccination by mucosal routes," TRENDS in Biotechnology 19(8):293-304 (2001)	
	C115	SCOTT, et al., Toxicity of Interferon, Vol. 282, pp. 1345-1348, British Medical Journal, April 25, 1981	

**EXAMINER****DATE CONSIDERED**

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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3763

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	T
	C116	SEFERIAN et al., "Immune stimulating activity of two new chitosan containing adjuvant formulations," <i>Vaccine</i> 19:661-668 (2001)	
	C117	SHUTE, "Second thoughts on the flu vaccine," <i>Science &amp; Society; Public Health</i> 137(17):80	
	C118	SINGLA et al., 2001, "Chitosan: Some pharmaceutical and biological aspects - an update," <i>J. Pharmacy and Pharmacol.</i> 53:1047-1067	
	C119	SMITH, "Low-dose vaccine helps block flu, study says younger adults seen benefiting," <i>The Boston Globe: National/Foreign A2</i> (2004 Nov. 4)	
	C120	Smith Kline Beecham Meeting Agenda	
	C121	STEINMAN, "The Dendritic Cell System and Its Role in Immunogenicity," <i>Annu Rev Immunol</i> ; 1991;9:271-96	
	C122	SUPERSAXO, et al., Recombinant Human Interferon Alpha-2a: Delivery to Lymphoid Tissue by Selected Modes of Application, <i>Pharmaceutical Research</i> , Vol. 5, No. 8, pp. 472-476, August 1998	
	C123	SUTHEREST, Treatment of Pruritus Vulvae by Multiple Intradermal Injections of Alcohol. A Double-Blind Study, Vol. 86, pp. 371-373, <i>British Journal of Obstetrics and Gynecology</i> , May 1979	
	C124	SVEINSSON, 1939, Investigation on the Influence of Insulin and Adrenalin in Rabbits with Alimentary Fatty Liver and Muscles and on the Content of Fat and Sugar in Blood, Oslo, Norway (pp. 66-86)	
	C125	TAKAYAMA et al., 1991, "Adjuvant activity of non-ionic block copolymers. V. Modulation of antibody isotype by lipopolysaccharides, lipid A and precursors," <i>Vaccine</i> 9(4):257-265	
	C126	TAURASO et al. Effect of dosage and route of inoculation upon antigenicity of inactivated influenza virus vaccine (Hong Kong strain) in man. <i>Bull. World Health Organ.</i> 1969;41(3):507-16	
	C127	The American Heritage College Dictionary, 2000, 3 <sup>rd</sup> Edition; Houghton Mifflin Company, Boston, New York, p. 368	
	C128	The Merck Manual of Diagnosis and Therapy, 1999, 17 <sup>th</sup> Edition, Beers & Berkow, ed., Merck Research Laboratories, Division of Merck & Co., Inc., Whitehouse Station, NJ, pp. 2559-2567	
	C129	TODD et al., 1997, "Development of an adjuvant active nonionic block copolymer for use in oil-free subunit vaccines formulation," <i>Vaccine</i> 15:564-570	
	C130	TODD et al., 1998, "Systematic development of a block copolymer adjuvant for trivalent influenza virus vaccine," <i>Dev. Biol. Stand.</i> 92:341-351	
	C131	VAN DER LUBBEN et al., "Chitosan and its derivatives in mucosal drug and vaccine delivery," <i>European Journal of Pharmaceutical Sciences</i> 14:201-207 (2001)	
	C132	VAN DER LUBBEN et al., "Chitosan for mucosal vaccination," <i>Advanced Drug Delivery Reviews</i> 52:139-144 (2001)	
	C133	VERHEUL et al., 1992, "Nonionic block polymer surfactants as immunological adjuvants," <i>Res. Immunol.</i> 143(5):512-519, discussion pp. 574-576	
	C134	VOGEL et al., 1995, "A compendium of vaccine adjuvants and excipients," in M.F. Powell, M.J. Newman (eds.) Plenum Press, New York pp. 141-228	
	C135	VON HOEGEN, "Synthetic biomimetic supra molecular Biovector™ (SMBV™) particles for nasal vaccine delivery," <i>Advanced Drug Delivery Reviews</i> 51:113-125 (2001)	
	C136	WARD, et al., Puritus Vulvae: Treatment by Multiple Intradermal Alcohol Injections, Vol. 93, No. 2, pp. 201-204, <i>British Journal of Dermatology</i> , August 1975	
	C137	WESTERINK et al., "ProJuvant™ (Pluronic F127®/chitosan) enhances the immune response to intranasally administered tetanus toxoid," <i>Vaccine</i> 20:711-723 (2002)	

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



<b>LIST OF REFERENCES CITED BY APPLICANT</b> (Use several sheets if necessary)	ATTY. DOCKET NO. <b>11219-029-999</b> (500752-999028, P-5331)	APPLICATION NO.  <b>10/679,038</b>
	APPLICANT <b>Mikszta et al.</b>	
	FILING DATE <b>October 2, 2003</b>	ART UNIT <b>3763</b>

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	T
	C138	WHITTLE et al., "Trials of Intradermal Hepatitis B Vaccines in Gambian Children," Ann Trop Paediatr; 1987 Mar;7(1):6-9	
	C139	WOODLEY, 2001, "Bioadhesion: New possibilities for drug administration?" Clin. Pharmacokinet. 40(2):77-84	
	C140	WU, et al., Pharmacokinetics of Methoxyflurane after its Intra-Dermal Injection as Lecithin-Coated Microdroplets, Vol. 9, pp. 1-12, Journal of Controlled Release, July 1989	
	C141	ZAYNOUN, et al., The Effect of Intracutaneous Glucocorticoids on Plasma Cortisol Levels, Vol. 88, No. 2, pp. 151-156, British Journal of Dermatology, February 1973	
	C142	ZIGTERMAN et al., 1987, "Adjuvant effects of nonionic block polymer surfactants on liposome-induced humoral immune response," J. Immunol. 138(1):220-225	

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